PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Bozidar Ferek-Petric	Examiner:	Mehta, Bishma
Serial No.	10/695,848	Group Art Unit:	3767
Filing Date:	October 29, 2003	Docket No.:	P0010438.01
Title:	IMPLANTABLE ELECTROPORATION THERAPY DEVICE AND METHOD FOR USING SAME		

Appeal Brief

COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The following Brief is submitted pursuant to the Notice of Appeal mailed February 4, 2009.

Any required fee will be made at the time of submission via EFS-Web. In the event fees are not or cannot be paid at the time of EFS-Web submission, please charge any fees under 37 CFR § 1.16, 1.17, 1.136(a), or any additional fees to Deposit Account 13-2546.

I. Real party in interest

The real party in interest in this application is Medtronic, Inc, assignee of the application.

II. Related appeals and interferences

None

III. Status of the claims

Claims 46 – 48, 50 – 52, 54 – 59 and 61 - 67 stand rejected as of the Advisory Action of March 10, 2009. The rejections of claims 46 – 48, 50 – 52, 54 – 59 and 61 are appealed.

Claims 1 - 45, 49, 53, 60 and 68 - 83 have been cancelled.

IV. Status of amendments

Based on the Advisory Action of January 29, 2009, the amendment filed January 5, 2009 has been entered responsive to the Notice of Appeal filed February 4, 2009.

The Appendix of Claims below reflects the claims as so amended. Errors in the prior transcription of the claims, as noted in the Advisory Action of March 10, 2009, have also been corrected.

V. Summary of claimed subject matter

Claims 46 – 48, 50 – 52, 54 – 59 and 61 - 67 stand rejected. The subject matter of these claims is summarized below, by means of a discussion of the two independent claims 46 and 58. Patentability of the dependent claims is not separately argued. No claims have been rejected under Section 112

Claim 46 is directed to a method for treating a cancerous tumor. See Abstract

The method includes implanting a wholly-implantable electroporation device wholly within a body, the device including a drug reservoir and operative control circuitry both disposed within its housing. See Page 4, line 25 to page 5, lines 25 - 30, Page 5, lines 20 – 25. See also Figure 2.

The method further includes delivering a drug to the body and proximate the cancerous tumor via a fluid conduit coupled to the drug reservoir. See page 5, lines 20 – 25, Figure 2 page 12, line 28 – page 13, line 4 and page 13, lines 16 – 23.

The method further includes delivering at least one electrical pulse having an electrical field strength of from about 700 V/cm to about 1500 V/cm and said electrical pulse has a pulse width of from about 50 microseconds to about 200 microseconds across at least a portion of the cancerous tumor. See page 4, lines 5 – 11 and page 11, line 10 – page 11, line 2.

The method finally includes detecting a qRs complex from an electrogram of the body and synchronizing the delivering of the at least one electrical pulse with the qRs complex. See page 5, lines 20 – 25, Figure 2 page 12, line 28 – page 13, line 4 and page 13, lines 16 – 23.

Claim 58 also describes a method for treating cancer. See Abstract.

The claimed method includes implanting a wholly-implantable electroporation device in a body operable to selectively electroporate tissue within the body. See Page 4, line 25 to page 5, lines 25 - 30, Page 5, lines 20 – 25. See also Figure 2. Electroporation is done using at least one lead having at least one wholly implantable therapy electrode and by locating the electrode in or proximate a cancerous tumor. See page 8, lines 14 – 20, Figure 2 and page 11, line 10 – page 11, line 2.

The method requires applying a high frequency stimulus in the vicinity of the cancerous tumor with the at least one wholly-implantable first therapy electrode, thereby raising a temperature in the vicinity of the cancerous tumor. See page 17, lines 4 – 20.

The method further includes delivering a drug to the body in the vicinity of the cancerous tumor. See page 5, lines 20 – 25, Figure 2 page 12, line 28 – page 13, line 4 and page 13, lines 16 – 23. The electroporation therapy delivered includes at least one electrical pulse in the vicinity of the cancerous tumor, wherein said at least one electrical pulse produces an electrical field strength of from about 700 V/cm to about 1500 V/cm and has a pulse width of from about 50 microseconds to about 200 microseconds. See page 4, lines 5 – 11.

The method finally requires detecting a qRs complex from an electrogram of the body and synchronizing the delivering of the at least one electrical pulse with the qRs

complex. See page 5, lines 20 – 25, Figure 2 page 12, line 28 – page 13, line 4 and page 13, lines 16 – 23.

VI. Grounds of rejection to be reviewed on appeal

A. The Final Office Action of November 4, 2008 rejected claims 46 – 48, 50 – 52, 56 and 57 under Section 103(a) as unpatentable over Whitehurst, et al. (US Patent No. 6,733,485) in view of Houben, et al.(US Patent No. 6,261,280). This ground of rejection is respectfully traversed.

B. The Final Office Action of November 4, 2008 rejected claims 54 and 55 under Section 103(a) as unpatentable over Whitehurst, et al. (US Patent No. 6,733,485) in view of Houben, et al.(US Patent No. 6,261,280) in view of Sterzer (US Patent N. 5,386,837). This ground of rejection is respectfully traversed.

C. The Final Office Action of November 4, 2008 rejected claims 58, 59, 63 – 65 and 67 under Section 103(a) as unpatentable over Weaver (US Patent No. 5,389,069) in view of Houben, et al.(US Patent No. 6,261,280) and Sterzer (US Patent N. 5,386,837). This ground of rejection is respectfully traversed.

D. The Final Office Action of November 4, 2008 rejected claims 61, 62 and 66 under Section 103(a) as unpatentable over Weaver (US Patent No. 5,389,069) in view of Houben, et al.(US Patent No. 6,261,280) and Sterzer (US Patent N. 5,386,837) in view of Whitehurst, et al. (US Patent No. 6,733,485) This ground of rejection is respectfully traversed.

VII. Argument

A. Whitehurst, et al and Houben, et al.

All rejections under grounds A and B and perhaps D above are based upon the argument that Houben, et al. makes it obvious to add qRs synchronization to Whitehurst, et al., and thus produce the claimed invention as broadly claimed. However, this argument ignores the fact that synchronization in Houben, et al. is for a purpose completely inapplicable to the device of Whitehurst, et al. In Houben, et al. synchronization is provided to enable the sensing of signals (qRs complexes) from the tissue (the heart) produced in response to the applied treatment pulses. There several reasons why the argument for rejection is believed to be incorrect.

First, there is no sensed signal analogous to the qRs complex as sensed in Hoube, et al. disclosed in Whitehurst, et al. Unlike the heart, treated by the Houben, et al device, the tumor tissue treated by the device in Whitehurst, et al. does not generate electrical signals to which treatment pulses can be synchronized or which are generated in response to the application of treatment signals. It is respectfully asserted that the teaching of Houben, et al. thus suggests there would be no benefit to any synchronization in a device as in Whitehurst, et al., teaching directly away from the invention as claimed in all pending claims. Certainly the rationale for synchronizing to qRs complexes presented by Houben, et al is inapplicable to the device of Whitehurst, et al.

Second, there is no teaching in Whitehurst, et al that the timing of the delivery of treatment pulses should be synchronized to any particular events or parameters whatsoever and no suggestion of any benefit that might be associated therewith.

Third, while the Whitehurst device does sense various parameters, most of them are chemical levels which do not provide any corresponding mechanism for facilitating synchronization of delivered treatment pulses thereto. While some form of closed loop control is discussed, it is believed that control of frequency, amplitude, duration of treatment pulses and/or general timing of therapy periods is intended, rather than control of timing of individual pulses or pulse bursts. See Column 21, lines 5 - 54. If there is asserted to be an obvious way to synchronize timing of delivery of treatment pulses to a pH level, for example, or how it would be beneficial in the context of treatment of a tumor, it is not disclosed. The same is true for the other sensed chemical parameters listed. The rationale of Houben, et al., clearly does not apply to and teaches away from the need for such synchronization. Even if there were some obvious benefit to synchronization of the treatment pulses in Whitehurst, et al. to sensed chemical levels, the resultant device would not much resemble the apparatus as presently claimed. In any case, whatever rationale for such synchronization could be gleaned from Whitehurst, et al. would not apply to synchronization of the tumor treatment pulses to qRs complexes.

Fourth, while Whitehurst does disclose sensing of an electrical physiologic parameter, perhaps using the stimulation electrode, the only electrical parameter specifically listed is an electro-myographic signal (EGM). These signals are emitted by skeletal muscles, not by the tumor being treated. Again, there is no disclosed mechanism for synchronizing delivery of treatment pulses to such sensed signals and no disclosed or obvious reason to do so. The rationale of Houben, et al., clearly does not apply to and teaches away from the need for such synchronization. Even if there were some obvious benefit to synchronization of the treatment pulses in Whitehurst, et al. to EMG signals, the resultant device would still not much resemble the apparatus as presently claimed. In any case, whatever rationale for such synchronization could be gleaned from Whitehurst, et al. would not apply to synchronization of the tumor treatment pulses to qRs complexes.

Sterzer is not cited for and does not address the deficiencies of Whitehurst, et al. in view of Houben, et al as discussed above.

Reversal of the rejections based upon grounds A, B and D listed above is therefore respectfully requested.

B. Weaver and Houben, et al.

All rejections under grounds C and D above are expressly based upon the argument that Houben, et al. makes it obvious to add qRs synchronization to Weaver, and thus produce the claimed invention as broadly claimed. However, this argument fails for the reasons discussed above in conjunction with Whitehurst, et al. Weaver, like Whitehurst, et al. treats tumors and contains no suggestion of synchronizing treatment signals to qRs complexes. Weaver, like Whitehurst, et al., contains no teaching that the rationale for synchronizing treatment pulses to qRs complexes in Houben, et al. has any applicability whatsoever. Further, unlike Whitehurst, et al, Weaver is not even cited as providing any signals useful for synchronization. For the first and second reasons as discussed above in conjunction with Whitehurst, et al. and Houben, et al., the combination of Weaver and Houben, et al. is similarly not believed to render the invention as claimed obvious.

Sterzer is not cited for and does not address the deficiencies of Weaver in view of Houben, et al. as discussed above.

Reversal of the rejections under grounds C and D is respectfully requested.

The addition of Whitehurst, et al to the combination of Weaver and Houben, et al., as in ground D, does not remedy the deficiencies of Weaver, for the third and fourth reasons discussed above in conjunction with Houben, et al and Whitehurst, et al..

Withdrawal of the rejections based upon ground D for this reason as well is respectfully requested.

The Commissioner is authorized to charge any deficiencies and credit any overpayments to Deposit Account No. 13-2546 for entry of the instant Response.

Respectfully submitted,

Date: April 6, 2009

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VIII. Claims Appendix

The claims, as amended by the response of January 5, 2009, are as follows:

1.-45. Canceled

46. A method for treating a cancerous tumor, comprising:

implanting a wholly-implantable electroporation device wholly within a body, wherein said wholly-implantable electroporation device includes a drug reservoir and operative control circuitry both disposed within a housing for said wholly-implantable electroporation device;

delivering a drug to the body and proximate the cancerous tumor via a fluid conduit coupled to the drug reservoir;

delivering from the wholly-implantable electroporation device, at least one electrical pulse across at least a portion of the cancerous tumor, wherein said at least one electrical pulse produces an electrical field strength of from about 700 V/cm to about 1500 V/cm and said at least one electrical pulse has a pulse width of from about 50 microseconds to about 200 microseconds; and

detecting a qRs complex from an electrocardiogram of the body and synchronizing the delivering of the at least one electrical pulse with the qRs complex..

47. The method of claim 46, further comprising:

sensing at least one biological parameter and providing a sense signal based on the biological parameter; and

conveying said parameter to said operative control circuitry disposed within the housing of the device.

48. The method of claim 47, further comprising controlling delivery of the at least one

electrical pulse based on the sense signal.

49. Cancelled

50. The method of claim 46, further comprising measuring impedance across a portion of the cancerous tumor and comparing the impedance to a threshold impedance value.

51. The method of claim 50, further comprising suspending delivery of additional electrical pulses based on a result of comparing the impedance to the threshold impedance value.

52. The method of claim 46, wherein delivering the drug to the body comprises delivering the drug via an external drug delivery apparatus.

53. Cancelled

54. The method of claim 46, further comprising increasing a temperature of the body in the vicinity of the cancerous tumor prior to delivering the at least one electrical pulse.

55. The method of claim 54, wherein increasing the temperature of the body in the vicinity of the cancerous tumor comprises delivering a high frequency stimulus with the electroporation device.

56. The method of claim 46, further comprising programming the electroporation device to deliver a particular therapy profile.

57. The method of claim 56, wherein programming the electroporation device occurs after implantation.

58. A method for treating cancer, comprising:

implanting a wholly-implantable electroporation device in a body, the wholly-implantable electroporation device operable to selectively electroporate tissue within the body using at least one lead having at least one wholly implantable therapy electrode associated therewith; and locating the at least one wholly implantable therapy electrode in or proximate a cancerous tumor;

applying a high frequency stimulus in the vicinity of the cancerous tumor with the at least one wholly-implantable first therapy electrode, thereby raising a temperature in the vicinity of the cancerous tumor;

delivering a drug to the body in the vicinity of the cancerous tumor; and

delivering, with the wholly-implantable electroporation device, at least one electrical pulse in the vicinity of the cancerous tumor, wherein said at least one electrical pulse produces an electrical field strength of from about 700 V/cm to about 1500 V/cm and has a pulse width of from about 50 microseconds to about 200 microseconds; and

detecting a qRs complex from an electrocardiogram of the body and synchronizing the delivering of the at least one electrical pulse with the qRs complex.

59. The method of claim 58, further comprising sensing the temperature in the body and providing a sense signal based on the temperature.

60. Cancelled

61. The method of claim 58, further comprising measuring impedance across a portion of the cancerous tumor and comparing the impedance to a threshold impedance value.

62. The method of claim 61, comprising suspending delivery of additional electrical pulses based on a result of comparing the impedance to the threshold impedance value.

63. The method of claim 58, wherein delivering the drug to the body comprises delivering the drug through a drug catheter coupled to a housing of the electroporation device, the drug catheter in fluid communication with a drug reservoir located within the housing.

64. The method of claim 58, wherein delivering the drug to the body comprises delivering the drug via an external drug delivery apparatus.

65. The method of claim 58, wherein the cancerous tumor is a breast carcinoma.

66. The method of claim 58, wherein the cancerous tumor is a osteosarcoma.

67. The method of claim 58, wherein delivering the at least one electrical pulse comprises delivering about four to about eight electrical pulses.

68.-83. Cancelled

IX. Evidence Appendix

None.

X. Related Proceedings Appendix

None.